UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel.* TUESDAE STAINBROOK, D.O., M.P.H., MARY SIMPSON, M.B.A., and JONATHAN POPE, M.D., Ph.D., Plaintiffs, v. BROOKVILLE HOSPITAL, CLEARFIELD HOSPITAL, DUBOIS REGIONAL MEDICAL CENTER, ELK REGIONAL HEALTH CENTER, INC., GARY OTT, M.D., PENN HIGHLANDS HEALTHCARE, and WOMEN'S CARE OF WESTERN PENNSYLVANIA, LLC , Defendants.	C.A. No.: 16-244E **FILED UNDER SEAL** pursuant to 31 U.S.C. § 3729 *et seq.*

COMPLAINT

Tuesdae Stainbrook, D.O., M.P.H., Mary Simpson, M.B.A., and Jonathan Pope, M.D. ("Relators") on behalf of themselves and the United States, bring this action under the False Claims Act, 31 U.S.C. §§ 3729-3732, to recover all damages, penalties and other remedies available under the Act.

INTRODUCTION

1. Relators bring this action on behalf of the United States of America against Defendants for treble damages and civil penalties arising from Defendants' false statements and false claims in violation of the Civil False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (the "FCA").

2. As set forth herein, the Defendants have created a culture where money – not medicine – drives the decision making process at Penn Highlands Healthcare, Inc and where profits trump patient safety. Defendants' illegal and fraudulent conduct consists of knowingly submitting false claims to Medicare, Medicaid, and other federal health insurance programs by, inter alia, billing for services that resulted from referrals made in violation of the Stark law and the Anti-Kickback Statute ("AKS").

3. Penn Highlands Healthcare, Inc. and its affiliated hospitals, also billed for the services of non-physician practitioners and auxiliary personnel who were not properly enrolled as participating providers by routinely falsifying information in claim forms and submitting them on behalf of physicians who neither personally furnished the services billed, nor directly supervised such services, in violation of Medicare's "incident to" and "shared/split services" rules.

4. Defendant Hospitals also misrepresented the status of outpatient clinics in order to bill the federal programs at the higher reimbursement rates allowed for Rural Health Clinics.

5. Defendants also improperly channeled patients to its critical access hospital in order to bill Medicare at higher reimbursement rates for "swing-bed" services.

6. Defendants have knowingly engaged in the illegal and fraudulent billing practices described herein for their own financial reward to the detriment of patient care.

7. The False Claims Act provides that any person who knowingly submits or causes to be submitted to the United States for payment or approval a false or fraudulent claim is liable to the government for a civil penalty of not less than $5,500 and not more

than $11,000 for each such claim, plus three (3) times the amount of damages sustained by the government because of the false claim and attorneys fees.

8. The Act allows any persons having knowledge of a false or fraudulent claim against the Government to bring an action in Federal District Court for themselves and for the United States Government and to share in any recovery as authorized by 31 U.S.C. § 3730. Relators claim entitlement to a portion of any recovery obtained by the United States as *qui tam* Relators/Plaintiffs. There are no bars to recovery under 31 U.S.C. § 3730(e), and, or in the alternative, Relators are an original source as defined therein.

9. Based on these provisions, Relators on behalf of the United States Government seek through this action to recover damages and civil penalties arising from the Defendants' submission of false claims for payment or approval to government entities for payment. Relators believe the United States has suffered millions of dollars in damages as a result of thousands of false claims submitted by the Defendants.

JURISDICTION AND VENUE

10. This action arises under the False Claims Act, 31 U.S.C. §§ 3729 *et seq*. This Court has jurisdiction over this case pursuant to 31 U.S.C. §§ 3732(a) and 3730(b). This Court also has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1345.

11. Venue is proper in the Western District of Pennsylvania pursuant to 31 U.S.C. § 3732(a) because acts proscribed by 31 U.S.C. §§ 3729 *et seq.* and complained of herein took place in this district, and is also proper pursuant to 28 U.S.C. § 1391(b) and

(c), because at all times material and relevant, Defendants transacted business in this District.

PARTIES

12. Tuesdae Stainbrook, D.O., M.P.H. is an adult individual who resides in Pennsylvania.

13. Mary Simpson, M.B.A. is an adult individual who resides in Pennsylvania.

14. Jonathan Pope, M.D. is an adult individual who resides in Ohio.

15. Relators are the original sources of this information to the United States. They have direct and independent knowledge of the information on which the allegations are based and have voluntarily provided the information to the United States before filing this action.

16. Defendant Penn Highlands Healthcare, ("Penn Highlands") is a Pennsylvania not-for-profit corporation operating a hospital system in north central and western Pennsylvania comprised of DuBois Regional Medical Center, Elk Regional Health Center, Inc., Clearfield Hospital and Brookville Hospital (collectively referred to as "the Hospital Defendants"). The system also includes Penn Highlands Physician Network, comprised of 200 providers and 85 clinics.

17. Defendant DuBois Regional Medical Center a/k/a Penn Highlands DuBois ("DRMC") is a Pennsylvania not-for-profit corporation operating a 214-bed hospital located in the City of DuBois, Clearfield County, Pennsylvania. DRMC is the flagship hospital for Penn Highlands.

18. Defendant Brookville Hospital a/k/a Penn Highlands Brookville is a Pennsylvania not-for-profit corporation operating a 35-bed Critical Access Hospital

located in Brookville, Jefferson County, Pennsylvania. Brookville Hospital is a subsidiary of DRMC.

19. Defendant Clearfield Hospital a/k/a Penn Highlands Clearfield is a Pennsylvania not-for-profit corporation operating a 96-bed hospital located in Clearfield, Clearfield County, Pennsylvania.

20. Defendant Elk Regional Health Center, Inc., a/k/a Penn Highlands Elk is a Pennsylvania not-for-profit corporation operating an 75-bed hospital, recently designated as a Critical Access Hospital ("CAH") in 2015, located in St. Marys and Ridgway, Elk County, Pennsylvania.

21. Defendant Gary Ott, M.D. is a physician with a specialty in obstetrics and gynecology. Dr. Ott owned and operated his own medical practice known as Women's Care of Western Pennsylvania, LLC.

22. Defendant Women's Care of Western Pennsylvania, LLC is a Pennsylvania limited liability company, which was located at 145 Hospital Avenue, Suite 315, DuBois, Pennsylvania that provided obstetrics and gynecological medical care and related services.

23. In 2011, 2012 and 2013, DRMC contracted with Dr. Ott, through Women's Care of Western Pennsylvania, LLC to provide medical director services as the Director of OB/GYN at DRMC. In 2013, DRMC purchased Women's Care of Western Pennsylvania, LLC for $600,000.

The Federal False Claims Act
31 U.S.C. §§ 3729-3732

24. The FCA provides for the award of treble damages and civil penalties for, *inter alia*, knowingly causing the submission of false or fraudulent claims for payment to the United States government. 31 U.S.C. § 3729 (a)(1).

25. 31 U.S.C. § 3729 of the Federal False Claims Act provides in pertinent part, that a person who

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G); . . . or (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,
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> * * *
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> Is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S. C. 2461 note: Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person . . ..
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> (b) For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.
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> 31 U.S.C. § 372

The Federal Healthcare Programs

26. The Defendants receive a significant portion of their revenue from the United States Government through Medicare, Medicaid and other federal health insurance programs.

The Medicare Program

27. The United States, through the Department of Health and Human Services ("HHS"), administers the Hospital Insurance Program for the Aged and Disabled established by Part A ("Medicare Part A Program") and the supplementary Medical Insurance Program established by Part B ("Medicare Part B Program"), Title XVIII, of the Social Security Act under 42 U.S.C. §§1395 *et seq*. The Medicare Part A and Medicare Part B programs are federally financed health insurance systems for persons who are aged 65 and over and those who are disabled.

28. HHS has delegated the administration of the Medicare program to CMS (formerly the Health Care Financing Administrator ("HCFA")), a component of HHS.

29. The Medicare Part A Program covers all inpatient hospital services provided to eligible persons, known as Medicare beneficiaries. In addition, the Part A Program covers certain home health services provided to Medicare beneficiaries who do not have Part B coverage. The Medicare Part B Program provides coverage for a wide range of inpatient and outpatient services, for physician and diagnostic services, for home health services for Part B eligible persons and for durable medical equipment. The Medicare Part B Program is a 100 percent federally subsidized health insurance system for disabled persons 65 years of age or older.

30. If health care services provided under either the Part A or Part B Program are reasonable and medically necessary, then the United States, through HHS-CMS, reimburses 80 percent of the reasonable cost of the service to either the Medicare beneficiary or the health service provider to whom the beneficiary's claim is assigned.

31. CMS assigns to private insurance carriers the task of administering and paying Medicare claims. In Pennsylvania, Novitas Solutions, Inc. is the Medicare Administrative Contractor (MAC). The MAC reviews and approves claims submitted for reimbursement by health services providers and oversees payment of those claims. The claims are paid with funds of the United States Treasury.

32. In order to establish eligibility to receive reimbursement from the Medicare program, CMS requires all hospitals to sign a Certification Statement as part of the Medicare Provider Agreement (CMS-855A Enrollment Application), which states in pertinent part,

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare.
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> * * *
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> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

Medicare Provider Agreement, Sec. 15 (Certification Statement) at ¶¶ 4, 6 (CMS-855A Enrollment Application (07-11)).

33. In order to establish eligibility to receive reimbursement from the Medicare program, CMS requires all physicians to sign a Certification Statement as part

of the Medicare Provider Agreement (CMS-855I Enrollment Application), which states in pertinent part,

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me or to the organization listed in Section 4A of this application. The Medicare laws, regulations, and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.
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> * * *
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> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

Medicare Provider Agreement, Sec. 15 (Certification Statement) at ¶¶ 4, 8 (CMS-855I Enrollment Application (07-11)).

34. The Hospital Defendants, as participants in the Medicare program, signed and submitted to CMS the Medicare Provider Agreement (CMS-855A) and required that their physicians sign and submit the CMS Medicare Provider Agreement for Physicians (CMS-855I), containing the language cited in paragraphs 36-37 herein, and indicating their agreement to be bound by the laws and regulations governing Medicare reimbursement for services.

35. Medicare requires providers to submit claims on paper or electronically using universal billing formats. Regardless of the format used, a provider's obligations to Medicare remain the same.

36. Beginning in 2007, paper claim submissions have been made using Medicare's UB-04 Uniform Bill (CMS 1450). The UB-04 (CMS-1450) notifies the provider, such as defendants, as follows:

> THE SUBMITTER OF THIS FORM UNDERSTANDS THAT MISREPRESENTATION OR FALSIFICATION OF ESSENTIAL INFORMATION AS REQUESTED BY THIS FORM, MAY SERVE AS THE BASIS FOR CIVIL MONETARY PENALTIES AND ASSESSMENTS AND MAY UPON CONVICTION INCLUDE FINES AND/OR IMPRISONMENT UNDER FEDERAL AND/OR STATE LAW(S).
>
> The form also requires entities submitting a claim to certify:
>
> Submission of this claim constitutes certification that the billing information as shown on the face hereof is true, accurate and complete. That the submitter did not knowingly or recklessly disregard or misrepresent or conceal material facts…

37. To submit claims electronically, which most providers, including defendants, are required to do; a provider must enroll in Medicare's Electronic Data Interchange (EDI) program. The enrollment process provides for the collection of the information needed to successfully exchange EDI transactions with Medicare and establishes the expectations of the parties to the exchange. The unique EDI number issued to a provider, along with its password, acts as the provider's electronic signature for claim submission.

38. As part of the EDI enrollment process, a provider is required to certify, among other things, that "it will submit claims that are accurate, complete, and truthful," that "it will acknowledge that all claims will be paid from Federal funds, that the submission of such claims is a claim for payment under the Medicare program, and that anyone who misrepresents or falsifies or causes to be misrepresented or falsified any record or other information relating to that claim that is required pursuant to this agreement may, upon conviction, be subject to a fine and/or imprisonment under applicable Federal law," and that "it will research and correct claim discrepancies." To complete its EDI enrollment, a provider representative must "certify that I have been

appointed an authorized individual to whom the provider has granted the legal authority to enroll it in the Medicare Program . . . and to commit the provider to abide by the laws, regulations and the program instructions of Medicare." *See* Medicare Claims Processing Manual, Ch. 24, § 30.2. Upon information and belief, Relators allege that defendants made these or similar certifications.

39. Once an institutional provider, such as the Hospital Defendants, has been enrolled in the EDI program, the provider submits Medicare claims electronically using CMS Form 837I. The electronic billing specifications and data elements prescribed by CMS for CMS-837I are consistent with the data elements present on the CMS UB-04 (CMS-1450) paper claim form.

40. The Hospital Defendants, as participants in the Medicare program, submitted their bills for services to Medicare using the UB-04 (CMS-1450), CMS-837I, or their equivalents, containing the language cited in paragraphs 36, 40, or 42 herein, or similar language, and indicating their agreement to be bound by the laws and regulations governing Medicare reimbursement for services, including but not limited to certification of compliance with 42 U.S.C. § 1395y(a)(1)(A).

41. Pursuant to the Medicare Provider Agreements, EDI Enrollment Agreements, UB-04 (CMS-1450), CMS-837I and/or similar documents, by submitting claims for Medicare reimbursement, defendants certified to CMS that those claims are for services provided in compliance with CMS and federal laws and regulations.

42. As a prerequisite to payment by Medicare, CMS (HCFA) requires hospitals to submit annually a form HCFA-2552, more commonly known as the Hospital

Cost Report. Cost Reports are the final claim that a provider submits to the fiscal intermediary for items and services rendered to Medicare beneficiaries.

43. After the end of each hospital's fiscal year, the hospital files its Hospital Cost Report with Medicare, stating the amount of reimbursement the provider believes it is due for the year. *See* 42 U.S.C. §1395g(a); 42 C.F.R. § 413.20. *See also* 42 C.F.R. § 405.1801(b)(1). Hence, Medicare relies upon the Hospital Cost Report to determine whether the provider is entitled to more reimbursement than already received through interim payments, or whether the provider has been overpaid and must reimburse Medicare. 42 C.F.R. §§ 405.1803, 413.60 and 413.64(f)(1).

44. The Hospital Defendants were, at all times relevant to this complaint, required to submit Hospital Cost Reports to Medicare.

45. Under the rules applicable at all times relevant to this complaint, Medicare, through its fiscal intermediaries, had the right to audit the Hospital Cost Reports and financial representations made by the Hospital Defendants to ensure their accuracy and preserve the integrity of the Medicare Trust Funds. This right includes the right to make retroactive adjustments to Hospital Cost Reports previously submitted by a provider if any overpayments have been made. 42 C.F.R. § 413.64(f).

46. Every Hospital Cost Report contains a "Certification" that must be signed by the chief administrator of the provider or a responsible designee of the administrator.

47. Since September 30, 1994, Medicare cost reports have required the following certification provision:

> I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

Form CMS-2552-92.

48. Subsequently, in or about 1996, the Hospital Cost Report was revised again to include the following notice:

> Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. Furthermore, if services identified in this report were provided or procured through the payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result.

49. Defendants were at all times familiar with the laws and regulations governing the Medicare Program, including requirements relating to the completion of cost reports.

50. Hospital Cost Reports submitted by the Hospital Defendants were, at all times material to this complaint, signed by the chief financial officer or other hospital official, who attested, among other things, to the certification quoted above.

51. To obtain Medicare reimbursement under Part B, providers submit claims using a form known as a CMS Form 1500 or the electronic equivalent. Among the information the provider includes on a CMS Form 1500 is certain five-digit codes, known as Current Procedural Terminology codes, or CPT codes, that identify the services rendered and for which the provider seeks reimbursement.

52. By submitting the CMS Form 1500, providers expressly certify that:

> "1) the information on this form is true, accurate and complete; 2) I have familiarized myself with all applicable laws, regulations and program instructions, which are available from the Medicare contractor; 3) I have provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision; 4) this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and Medicaid laws, regulations, and program instructions for payment, including but not limited to the Federal anti-kickback statute and the Physician Self-Referral

> law (commonly known as the Stark law); 5) the services identified on this form were medically necessary and personally furnished by me or were furnished incident to my professional service by my employee under my direct supervision, except as otherwise expressly permitted by Medicare or CHAMPUS regulations…"

53. Federal law specifically obligates every provider to return to the United States any payment that it improperly receives. A hospital is required to disclose all known errors and omissions in its claims for Medicare reimbursement (including its cost reports) to its fiscal intermediary.

54. It is a felony for an entity to conceal or fail to disclose errors in payments received from government-funded health insurance programs.

> Whoever . . . having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment . . . conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized . . . shall in the case of such a . . . concealment or failure . . . be guilty of a felony.
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> 42 U.S.C. § 1320a-7b(a)(3).

The Medicaid Program

55. Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled. The federal involvement in Medicaid is largely limited to providing matching funds and ensuring that states comply with minimum standards in the administration of the program.

56. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding, which is called federal financial participation (FFP). 42 U.S.C. §§ 1396, *et seq.*

57. The state directly reimburses physicians for services rendered, with the state obtaining the federal share of the payment from accounts, which draw on funds of

the United States Treasury. 42 C.F.R. §§ 430.0-430.30. The federal share of each state's Medicaid program varies state by state.

58. Enrolled providers of medical services to Medicaid recipients, including each of the Defendants, are eligible for reimbursement for covered medical services under the provisions of Title XIX of the 1995 Amendments to the Federal Social Security Act. By becoming a participating provider in Medicaid, enrolled providers, including the Defendants, agree to abide by the rules regulations policies and procedures governing reimbursement, and to keep and allow access to records and information by Medicaid. In order to receive Medicaid funds, enrolled providers, together with authorized agents, employees and contractors, are required to abide by all the provisions of the Social Security Act, the regulations promulgated under the Act, and all applicable policies and procedures promulgated by the relevant state agency responsible for administering the Medicaid program.

59. Like Medicare, a "claim" under Medicaid is only reimbursable if it is "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member". 42 C.F.R. § 402.3.

TRICARE/CHAMPUS

60. In 1967, the Department of Defense created the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS"), which is a federally funded medical program created by Congress. 10 U.S.C. § 1071. CHAMPUS beneficiaries include active military personnel, retired personnel, and dependents of both active and retired personnel. *Id.*

61. In 1995, the Department of Defense established TRICARE, a managed healthcare program, which operates as a supplement to CHAMPUS. *See* 32 C.F.R. §§ 199.4, 199.17(a). Since the establishment of TRICARE in 1995, both programs are frequently referred to collectively as TRICARE/CHAMPUS, or just "TRICARE."

62. Just as with Medicare and Medicaid, TRICARE providers have an obligation to provide services and supplies at only the appropriate level and "only when and to the extent medically necessary." 32 C.F.R. § 199.6(a)(5).

63. TRICARE's governing regulations, like Medicare's and Medicaid's requirements also are based upon "medical necessity." TRICARE's governing regulations require that services provided be "furnished at the appropriate level and only when and to the extent medically necessary," and such care must "meet[] professionally recognized standards of health care [and be] supported by adequate medical documentation . . . to evidence the medical necessity and quality of services furnished, as well as the appropriateness of the level of care." 32 C.F.R. 199.6(a)(5). In this respect, similar to Medicare and Medicaid, services provided at a level higher than the medically necessary are improper and violations of TRICARE. *Id.*

Federal Employee Health Benefits Program

64. The Federal Employee Health Benefits Program ("FEHBP") is a federally funded medical insurance program for federal employees, retirees, their spouses and unmarried dependent children under age 22, administered by the Office of Personnel Management ("OPM") pursuant to 5 U.S.C. §§ 8901, *et seq.* Through the OPM, the Government contracts with private health plans or "carriers" to deliver health benefits to its employees. Monies for the FEHBP are maintained in the Employees' Health Benefits

Fund ("Health Fund"), and are administered by OPM. 5 U.S.C. § 8909. Federal agencies and their employees contribute to the Health Fund to cover the total cost of health care premiums. 5 U.S.C. § 8906. The monies from the Health Fund are used to reimburse the carriers for claims they pay on behalf of FEHBP beneficiaries.

65. Like Medicare, Medicaid and TRICARE, FEHBP will not cover any treatment or surgery that is not medically necessary. 5 U.S.C. § 8902(n)(1)(A).

VIOLATIONS OF THE STARK STATUTE AND ANTI-KICKBACK STATUTE

Regulatory Framework for the Stark Statute

66. Enacted as amendments to the Social Security Act, 42 U.S.C. § 1395nn (commonly known as the "Stark Statute") prohibits a hospital (or other entity providing healthcare items or services) from submitting Medicare claims for payment based on patient referrals from physicians having a "financial relationship" (as defined in the statute) with the hospital. The regulations implementing 42 U.S.C. § 1395nn expressly require that any entity collecting payment for a healthcare service performed under a prohibited referral must refund all collected amounts on a timely basis 42 C.F.R. § 411.353.

67. The Stark Statute establishes the clear rule that the government will not pay for items or services prescribed by physicians who have financial relationships with other providers that do not satisfy an exception to the Stark Statute

68. The Stark Statute prohibits a hospital from submitting a claim to Medicare for "designated health services" that were referred to the hospital by a physician with whom the hospital has a "financial relationship," unless a statutory exception applies.

"Designated health services" include inpatient and outpatient hospital services. See 42 U.S.C § 1395nn(h)(6).

In pertinent part, the Stark Statute provides:

> (a) Prohibition of certain referrals
>
> (1) In general
> Except as provided in subsection (b) of this section, if a physician (or an immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then
>
> (A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and
>
> (B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).
>
> 42 U.S. C. § 1395nn (emphasis added)

69. The Stark Statute is a strict liability statute. If a financial relationship between a hospital and a physician does not strictly satisfy all requirements of an exception, then the physician is prohibited from making a referral to the hospital for designated health services, and the hospital is prohibited from submitting a claim to Medicare for such services.

70. Moreover, the Stark Statute provides that Medicare will not pay for designated health services billed by a hospital when the designated health services result from a prohibited referral under subsection (a). *See* 42 U.S.C. § 1395nn(g)(1).

71. "Financial relationship" includes a "compensation arrangement," which means any arrangement involving any remuneration paid directly or indirectly to a referring physician.

72. The Stark Statute and companion regulations contain exceptions for certain compensation arrangements. These exceptions include, among others, "bona fide employment relationships," "personal service arrangements," "fair market value arrangements," and "indirect compensation relationships."

73. Defendants have the burden of proving compliance with every element of an exception.

74. For example, under the exception for bona fide employment relationships, compensation arrangements must meet, *inter alia*, the following statutory requirements: (A) the amount of the remuneration is fair market value for services personally performed by the physician and not based on the value or volume of referrals, and (B) the remuneration would be commercially reasonable even in the absence of referrals from the physician to the hospital. *See* 42 U.S.C. § 1395nn(e)(2)(B) and (e)(2)(C).

75. In order to qualify for the exception for personal services arrangements, a compensation arrangement must meet, *inter alia*, the following statutory requirements: (A) the compensation does not exceed fair market value for services personally performed by the physician, and (B) is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties (unless it falls within a further physician incentive plan exception as described in the statute. *See* 42 U.S.C. § 1395nn(e)(2)(A)(v).

76. In order to qualify for the exception for fair market value compensation, there must be, *inter alia*, an agreement in writing, the agreement must set forth all services to be furnished, all compensation must be set in advance and consistent with fair market value for services personally performed by the physician, and the agreement must not take into consideration volume or value of referrals or other business generated by the referring physician, and the agreement must not violate federal or state law. 42 C.F.R. § 411.357(1).

77. In order to qualify for the Stark Statute's exception for indirect compensation arrangements, defined as any instance where compensation flows from the entity providing designated health services through an intervening entity and then to the referral source (see 42 C.F.R. § 411.354(c)(2)), there must be, *inter alia*, a written agreement, the compensation must be consistent with fair market value for services personally performed by the physician, and the compensation may not take into consideration the volume or value of referrals or other business generated by the referring physician, and the agreement cannot violate the Anti-Kickback Statute. *See* 42 C.F.R. § 411.357(p).

78. In order to qualify for the above exceptions, or any other exceptions under the Stark Statute, the defendants must prove that they have met every element of the exception.

79. The Stark Statute also applies to claims for payment under Medicaid, and federal funds may not be used to pay for designated health services through a state Medicaid program. *See* 42 U.S.C. § 1396b(s).

Regulatory Framework for the Anti-Kickback Statute

80. The Anti-kickback Statute, 42 U.S.C. § 1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence healthcare decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population.

81. To protect the integrity of the program from these difficult to detect harms, Congress enacted a *per se* prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback gave rise to overutilization or poor quality of care. First enacted in 1972, Congress strengthened the statute in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

82. The Anti-kickback Statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for federally-funded medical services, including services provided under the Medicare, Medicaid and (as of January 1, 1997) TRICARE programs. In pertinent part, the statute states:

> (b) Illegal remuneration
>
> > (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind --

> (A) In return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) In return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

Shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person --

> (A) To refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) To purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

Shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b).

83. Violation of the statute can also subject the perpetrator to exclusion from participation in federal health care programs and, effective August 6, 1997, civil monetary penalties of $50,000 per violation and three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7a(a)(7).

84. The Anti-Kickback Statute is violated where even one purpose of the payment is to induce referrals.

85. Any remuneration should be at fair market value for actual and necessary items furnished or services rendered based upon an arm's-length transaction and should not take into account, directly or indirectly, the value or volume of any past or future referrals or other business generated between the parties.

86. Arrangements under which physicians are (i) provided with items or services for free or less than fair market value; (ii) relieved of financial obligations they would otherwise incur, or (iii) provided with inflated compensation paid for items or services constitute kickbacks. OIG Supplemental Compliance Program Guidance for Hospitals, p. 4866.

87. The Anti-Kickback Statute and the OIG regulations have established a number of "safe harbors" for common business arrangements.

88. The referenced payments to Dr. Ott do not fall within any of the safe harbors.

89. The statute further provides that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of the False Claims Act." 42 U.S.C. § 1320a-7b(g).

Kickbacks paid for illegal patient referrals

90. During the period of time relevant hereto, DRMC was aware of the prohibitions against kickbacks and legal restrictions on financial relationships with physicians. Nevertheless, DRMC embarked on a strategy of paying kickbacks to and engaging in unlawful relationships with physicians to induce patient referrals.

91. During the period of time relevant hereto, Gary Ott, M.D. owned and operated Women's Care of Western Pennsylvania, LLC which was the largest OBGYN practice in the area and a high volume referral source for DRMC.

92. Beginning in approximately 2008, Dr. Ott devised a scheme to maximize his bargaining power and to enhance the value of his patient referrals. Specifically, Dr. Ott made it known throughout the community that he intended to open a "women's center" in DuBois that would offer a broad range of diagnostic and clinical services to women that would be in direct competition with DRMC. Dr. Ott discussed his plans openly with other members of the medical staff and hospital administrators.

93. In an effort to forestall competition in women's healthcare services in the DuBois, area and to prevent the loss of core business, DRMC negotiated a lucrative compensation arrangement with Dr. Ott that resulted in payments to Dr. Ott in excess of $3.2 million during the period from July 1, 2009 through June 30, 2013.

94. During the period from July 1, 2009 to June 30, 2010, DRMC paid Dr. Ott $243,600 and Women's Care of Western Pennsylvania, LLC $485,893 as compensation for medical directorship services and as compensation for services related to the Healthy Beginnings Program, a Medicaid program that provides medical assistance coverage for pregnant women and children of low income families.

95. During the period from July 1, 2010 to June 30, 2011, DRMC paid Women's Care of Western Pennsylvania, LLC $762,967 as compensation for medical directorship services and as compensation for services related to the Healthy Beginnings Program.

96. During the period from July 1, 2011 to June 30, 2012, DRMC paid Women's Care of Western Pennsylvania, LLC $646,424 as compensation for medical directorship services and as compensation for services related to the Healthy Beginnings Program.

97. During the period from July 1, 2012 to June 30, 2013, DRMC paid Women's Care of Western Pennsylvania, LLC $473,846 as compensation for medical director services and as compensation for services related to the Healthy Beginnings Program.

98. Finally, in 2013 DRMC purchased Women's Care of Western Pennsylvania, LLC from Dr. Ott and paid him $600,000. Shortly thereafter he moved out of the area and relocated to Pottstown, Pennsylvania.

99. The deal between DRMC and Dr. Ott, which resulted in lucrative medical directorships and an appointment to DRMC's Board of Directors, was a sham arrangement intended to disguise the actual purpose of DRMC to pay kickbacks to Dr. Ott to insure a steady stream of patient referrals for DRMC and the other Hospital Defendants.

100. The amounts paid by DRMC to Dr. Ott for the medical directorship services greatly exceeded the fair market value for such services and were commercially unreasonable.

101. The payment of $600,000 to Dr. Ott by DRMC to purchase Women's Care of Western Pennsylvania, LLC greatly exceeded the fair market value for the practice and was commercially unreasonable.

102. The arrangements between DRMC and Dr. Ott created a "financial relationship" under the Stark Law that do not meet the requirements of any exception.

103. The payments that DRMC made to Dr. Ott constitute remuneration under the Anti-kickback Statute, and were intended in whole or in part to induce or reward the referral of patients for services to be paid under federal healthcare programs.

104. During the period from July 1, 2009 to through December of 2013, Dr. Ott referred hundreds of Medicare and Medicaid patients to the Hospital Defendants for inpatient, outpatient and other designated health services as defined in the Stark law.

105. During the period from July 1, 2009 to through December of 2013, Medicare and Medicaid paid thousands of claims submitted by the Hospital Defendants in which Dr. Ott was identified as the referring, admitting or operating physician.

106. These are false claims because they were submitted in violation of the Stark Statute and because they were the result of remuneration provided in violation of the Anti-kickback Statute.

FRAUDULENT BILLING OF NON-PHYSICIAN SERVICES

Regulatory Framework for Billing Non-Physician Services

107. Under Medicare guidelines, the National Provider Identifier ("NPI") number used to bill Medicare must accurately reflect who provides the services.

108. Medicare offers the following two options for non-physician practitioners' services to be reimbursed by Medicare Part B: (a) direct billing and (b) so-called "incident to" billing.

a. Direct Billing

109. Direct billing occurs when services provided by an independently-credentialed non-physician practitioner are directly billed to Medicare under the non-physician practitioner's own NPI.

110. In accordance with the Health Insurance Portability and Accountability Act ("HIPAA"), CMS issues NPIs to healthcare providers, including non-physician practitioners, through which Medicare billing must occur.

111. The NPI is a unique identifier, but does not carry any information about the provider such as the state in which they practice or their medical speciality.

112. Reimbursement under the Medicare program for services and supplies provided directly by Medicare-approved non-physician practitioners and those rendered incident to physicians' services are subject to a fee schedule that sets the maximum amount payable in each area of Medicare's jurisdiction.

113. This Medicare Physician Fee Schedule (MPFS) is updated annually. *See* Centers for Medicare and Medicaid Services, CMS.gov, August 20, 2015, https://www.cms.gov/apps/physician-fee-schedule/.

114. If non-physician practitioners perform services that cannot qualify as "incident to" services as set forth below and instead provide services independently and without any physician involvement, those non-physician practitioners are required to enroll with Medicare and obtain their own NPI.

115. With a separate NPI, a non-physician practitioner may directly bill Medicare for services that they are licensed or certified to perform within the state.

116. When billing Medicare under non-physician practitioners' NPIs rather than a physician's NPI, the reimbursement rate by Medicare is only 85% of the MPFS. *See* 42 C.F.R. §§ 414.52, 414.56 and Medicare Claims Processing Manual ("MCPM") (Pub. 100-04) Chapter 12 - Physicians/Nonphysician Practitioners, §§ 110 and 120, (last rev. November 17, 2014), available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf.

b. "Incident To" Billing

117. Conversely, non-physician practitioners who perform services that are incident to a physician's course of treatment, which are known as "incident-to services," can bill Medicare for the services provided by the non-physician practitioner under the physician's NPI.

118. Unlike services that are directly billed to a non-physician practitioner's NPI, when a non-physician practitioner bills for services performed "incident to" a physician's course of treatment, the health care provider receives reimbursement equal to 100% of the MPFS if Medicare's strict incident-to guidelines are met. *See* 42 U.S.C § 1395x(s); 42 C.F.R. § 410.26; Medicare Benefits Policy Manual ("MBPM"), (Pub. 100-02) Chapter 15 - Covered Medical and Other Health Services, § 60.1 (last rev. February 13, 2015), available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf.

119. To qualify as incident-to services, a physician must personally perform an initial service and establish the physician-patient relationship and initiate the course of treatment of which the service being performed by the non-physician practitioner is an incidental part.

120. After the initial service, the physician does not need to be involved in each patient visit, but must continue to actively participate in the management of the course of treatment for the patient.

121. The physician need not be physically present in the patient's treatment room while the incident-to services are provided, but the physician must provide direct supervision.

122. Direct supervision requires, at a minimum, that the physician be present in the office suite to render assistance if necessary. *See* 42 C.F.R. § 410.26 and MBPM (Pub. 100-02) Chapter 15 - Covered Medical and Other Health Services, § 60.1 (last rev. February 13, 2015), available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/

downloads/bp102c15.pdf.

123. Therefore, if an non-physician practitioner sees a new patient or assesses an established patient for a new problem without any participation by a physician, the service must be billed under the non-physician practitioner's NPI, not the physician's.

124. A "split/shared" service is an encounter where a physician and an non physician practitioner from the same group each personally perform a portion of an E/M visit in a hospital inpatient, outpatient, and emergency department setting.

125. The split/shared service can be billed to Medicare using the physician's NPI only if the physician provides a face-to-face portion of the encounter.

126. If the physician does not provide a face-to-face encounter in the above-settings, billing to Medicare must be reported using the non-physician practitioner's NPI.

Billing for not properly supervised physician services

127. Penn Highlands Healthcare employs hundreds of physicians that are assigned to off-site clinics and offices.

128. Even though employed physicians are assigned to many of the off-site clinics and offices, these locations are not regularly staffed by physicians, and non-physician staff provided most of the services at these facilities on a regular basis.

129. Physicians are paid a substantial amount, typically $1,000 per month to sign charts of CRNPs without any face-to-face contact with the patient or the physician's physical presence in the clinical site.

130. Penn Highlands Healthcare regularly bills for services provided by non-physician practitioners in its clinics under the name and billing number of its physicians, even when the physician was not present on site to provide direct supervision as required by Medicare's "incident to" rules.

131. For example, on October 10, 2015, Medicare patient LRR was treated at the Penn Highland's Q-Care clinic at 621 South Main Street in DuBois, PA.

132. Even though LRR received treatment from a nurse practitioner, the service was billed under the name and provider number for Dr. Robert Usaitis, a physician employed by Penn Highlands Healthcare who maintained an office practice at 145 Hospital Avenue, several blocks from the clinic.

133. Dr. Usaitis did not furnish the medical service, nor did he directly supervise the services that were furnished by the nurse practitioner. In fact, patient LRR never met Dr. Usaitis, never had any contact with Dr Usaitis, and never had any previous association with Dr. Usaitis.

134. For Penn Highlands Healthcare or its affiliated companies to bill Medicare and other federal programs for a physician's service, that physician must certify that he or she personally furnished the services or that an employee furnished the services under the direct supervision of the physician.

135. Accordingly, the Penn Highlands Healthcare's bill to Medicare for LRR's office visit is a false and fraudulent claim, as are thousands of other similar bills submitted to Medicare and other federal healthcare programs under the name or billing number of on behalf of physicians who did not actually perform the services for which they are billing or did not provide direct supervision as required by the "incident to" rules. Moreover, the claims sought reimbursement for services of non-physician practitioners who were not properly enrolled as providers for such programs.

Not properly billing for split/shared physician services at DRMC

136. At its various hospitals, Penn Highlands Healthcare repeatedly violated the split/shared services rules related to the proper billing of physician services performed by non-physicians.

137. Similar to the "incident to" rules, which apply in the office setting, Medicare allows a non-physician to bill for physician E/M services in the hospital setting under the physician's billing number, but only where the physician and the NPP belong

to the same group and the physician has a face-to-face encounter with the patient before, during or after the NPP's visit with the patient.

138. In 2014, Relator Simpson was the interim Executive Director of the Free Medical Clinic operated by Penn Highlands Healthcare and served as Vice President of its Board of Directors. In that capacity, she contacted Joanne Genevaro, Penn Highland Healthcare's Director of Revenue Management and was incorrectly advised with regard to the rules for billing the services of Certified Registered Nurse Practitioners ("CRNPs") at her clinic. In an email dated August 29, 2014, Genevaro states, "Unfortunately as of now, Medicaid [sic] does not credential / recognize mid levels. All billings to Medicaid [sic] for services done by CRNP's or PA's have to be signed off on by the supervising physician and billed under the physician's ID#" (Genevro, 2014)."

139. Shortly thereafter in an email dated September 12, 2014 Genevaro implicitly acknowledged that Penn Highlands Healthcare had been improperly billing CRNP services as physician services, in violation of Medicare's "incident to" rules, stating as follows:

> My staff has done some more research on CRNPs and their ability to practice independent of a physician. CRNPs are permitted to practice in the state of PA independent of a physician as long as they have a written collaborative agreement with a licensed physician and the physician is readily available by phone or radio communication. Their scope of work is defined in their collaborative agreement which also includes their level of prescriptive authority. They are / can be recognized by MA and bill their services using their own NPI. Also, their collaborating physician is not required to cosign their notes. If I missed something or there is anything else you need help with please don't hesitate to call.

140. The Hospital Defendants have submitted thousands of claims to the Medicare, Medicaid and other federal healthcare programs that were false because they

misrepresented the identity of the providers, falsely claiming reimbursement under the name or billing number of on behalf of physicians who did not actually perform the services for which they are billing, and seeking reimbursement for services of non-physician practitioners who were not properly enrolled as providers for such programs.

141. Upon information and belief, the Hospital Defendants have not self-reported overcharges for violating the "incident to" rules, nor have they changed their practice of billing non-physician practitioner charges under the provider numbers of physicians that did not perform the services and were not present to supervise the services.

Billing for not properly supervised cardiac rehabilitation services

142. Medicare covers cardiac rehabilitation services under the benefit category "services incident to a physician's professional services." Social Security Act 1861(s)(2)(B).

143. As indicated above, "Incident to" services must be provided under direct physician supervision.

144. The relevant regulatory text, as referenced in the NCD is:

> "Direct supervision" means the physician must be present and on the premises of the location and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean the physician must be present in the room when the procedure is performed." 42 CRF §410.27 (emphasis added)

145. At all times material hereto the cardiac rehabilitation services at DRMC were performed by Registered Nurses ("RNs") or Cardiac Rehab Therapists ("CRTs").

146. At least as early as August of 2012, and continuing to at least August of 2014, Dr. Steven Graeca served as the director of the cardiac rehabilitation program at DRMC but rarely visited the cardiac rehabilitation facility.

147. During this time Dr. Graeca maintained his private medical office practice at 145 Hospital Avenue, Suite 215, DuBois, PA.

148. During this time, Dr. Graeca was regularly attending to patients in his office while DRMC was operating its cardiac rehabilitation facility at a separate location without direct supervision by Dr. Graeca or other qualified physician, in violation of Medicare's direct supervision requirement.

149. For example, beginning in July 2012, Medicare patient MES received cardiac rehabilitation services at DRMC.

150. MES attended 31 sessions and DRMC billed Medicare over $4,000.00 under Dr. Graeca's provider number, even though Dr. Graeca did not provide the medical services and did not directly supervise those services. While later trying to retrieve her medical records from Dr. Graeca, MES' s daughter was advised by a rehab nurse that Dr. Graeca only visits the facility once a month, and then only to sign charts.

151. Even though Dr. Graeca did not perform or supervise the cardiac rehab treatment, and was routinely not in the building while cardiac rehabilitation services were being performed, DRMC submitted all cardiac rehabilitation billing under Dr. Graeca's provider number.

152. The Hospital Defendants have submitted thousands of claims to the Medicare, Medicaid and other federal healthcare programs that were false because they misrepresented the identity of the providers, falsely claiming reimbursement under the

name or billing number of on behalf of physicians who did not actually perform the services for which they are billing, and seeking reimbursement for services of non-physician practitioners who were not properly enrolled as providers for such programs.

153. Upon information and belief, the Hospital Defendants have not self-reported overcharges for violating the cardiac rehabilitation supervision rules, nor have they changed their practice of billing non-physician practitioner charges under the provider numbers of physicians that did not perform the services and were not present to supervise the services.

MISUSE OF RURAL HEALTH CLINIC DESIGNATION

Regulatory framework for Rural Health Clinics

154. Rural Health Clinics ("RHCs") were established by the Rural Health Clinic Service Act of 1977 to address an inadequate supply of physicians serving Medicare beneficiaries in underserved rural areas, and to increase the utilization of nurse practitioners and physician assistants in these areas.

155. RHCs are eligible to participate in the Medicare program and are paid an all-inclusive rate ("AIR") per visit for primary health services and qualified preventive health services.

156. RHCs are defined in section 1861(aa)(2) of the Social Security Act as facilities that are engaged primarily in providing services that are typically furnished in an outpatient clinic.

157. To be eligible for certification as an RHC, a clinic must be located in a non-urbanized area, as determined by the U.S. Census Bureau, and an area designated or

certified within the previous 4 years by the Secretary, HHS, in any one of the four types of designated shortage areas.

158. RHCs may be permanent or mobile units. If clinic services are furnished at permanent units in more than one location, each unit is independently considered for approval as a rural health clinic.

159. The main advantage of RHC status is enhanced reimbursement rates for providing Medicaid and Medicare services. For certified RHCs, Medicare visits are reimbursed based on reasonable costs and Medicaid visits are reimbursed under a cost-based method or an alternative Prospective Payment System (PPS).

Outpatient clinic visits improperly billed as RHC services

160. In 2015, the Hospital Defendants embarked on a strategy to exploit the reimbursement advantage of RHCs by expanding the number of off-site outpatient clinics and billing the services as RHC services, regardless of their actual status.

161. At all times material hereto, the Hospital Defendants operated outpatient clinics at various locations throughout their service area including; QCare Punxsutawney in Punxsutawney, PA, QCare Moshannon Valley in Phillipsburg, PA, QCare DuBois in DuBois, PA, The Clinic at Walmart in DuBois, PA, QCare Cameron County in Emporium, PA, QCare Ridgway in Ridgway, PA, and QCare St. Marys in St. Marys, PA.

162. In addition to the above outpatient clinics, the Hospital Defendants operated three certified RHCs as follows:

Allegheny Health Center
22 Industrial Park Road, Brookville, PA

Penn Highlands Brookville Family Practice New Bethlehem
1323 Brookville Street, Fairmont City, PA

Penn Highlands Brookville Marienville Family Practice
125 Chestnut Street, Marienville, PA

163. Initially Penn Highlands Healthcare listed all of the outpatient clinics, the officially certified RHCs and the QCare clinics, as rural health clinics on the Pennsylvania Department of Health website. After it was advised that QCare Punxsutawney had been improperly listed as a RHC on the Department of Health's website because it had not been certified or officially designated by CMS, Penn Highlands Healthcare devised another subterfuge.

164. Pursuant to the alternate scheme, Defendant Penn Highlands Healthcare misrepresented the identity of the provider on medical records, bills and correspondence related to QCare patients in its Punxsutawney Moshannon Valley clinics. Specifically, New Bethlehem Family Health was routinely identified as the provider on numerous medical records and billing documents relating to patients that were treated at Punxsutawney QCare and other QCare clinics that were not certified RHCs.

165. By falsely designating New Bethlehem Family Health as the provider for QCare patients, Defendant Penn Highlands Healthcare was reimbursed at a higher rate than it would otherwise have been entitled.

166. For example, on February 2, 2016, Medicaid patient RNJ received treatment at Penn Highlands Healthcare's Punxsutawney QCare clinic. Even though the medical records clearly indicate that the "location of care" was the Punxsutawney QCare clinic, the billing provider is identified as New Bethlehem Family Health, 1323 Brookville Street in Fairmont City, PA, one of Penn Highlands' certified RHCs.

167. In another example, on January 24, 2016, Medicaid patient JJA received treatment at Penn Highlands Healthcare's Punxsutawney QCare clinic. Even though the

medical records clearly indicate that the "location of care" was the Punxsutawney QCare clinic, the billing provider is identified as New Bethlehem Family Health, 1323 Brookville Street in Fairmont City, PA, one of Penn Highlands Healthcare's certified RHCs.

168. In another example, on February 3, 2016, Medicaid patient ALH received treatment at Penn Highlands Healthcare's Punxsutawney QCare clinic. As with the previous two examples, even though treatment was provided at the Punxsutawney QCare clinic, the billing provider is identified as New Bethlehem Family Health, 1323 Brookville Street in Fairmont City, PA, one of Penn Highlands Healthcare's certified RHCs.

169. When questioned by the medical staff, John Suitka, President of DRMC explained that the Q-cares were designated as Rural Health Clinics to obtain a higher reimbursement and because they could be staffed by non-physicians. He also explained that the clinics are set up through Brookville Hospital, which, as a certified critical access hospital, allows for an even higher reimbursement.

170. Services at QCare Moshannon Valley are billed through Brookville Hospital, even though it is over 56 miles from the clinic; by comparison, the clinic is located only 38 miles from Clearfield Hospital, which does not have a critical access designation.

171. As indicated above, the primary benefit of RHC status is enhanced reimbursement from Medicare and Medicaid. There are two types of RHCs: independent RHCs and provider based RHCs. Provider based RHCs work as a department of another provider, such as a CAH, providing health care services to the same population. Because

RHCs are reimbursed on the basis of allowable and reasonable costs, there are significant reimbursement advantages from achieving provider based RHC status associated with a CAH.

172. As a result of the above scheme the Hospital Defendants have submitted thousands of false claims to the Medicare, Medicaid and other federal health insurance programs.

MISUSE OF CRITICAL ACCESS HOSPITAL DESIGNATION

Enhanced reimbursement for CAHs providing "swing-bed" services

173. Congress established the Rural Flexibility Program, which created Critical Access Hospitals ("CAHs") to ensure that beneficiaries in rural areas have access to a range of hospital services.

174. CAHs have broad latitude in the types of inpatient and outpatient services they provide, including "swing-bed" services, which are the equivalent of services performed at a skilled nursing facility. "Swing-bed" is a reimbursement term that means the care and reimbursement for the care of a patient in a small rural hospital or CAH "swings" from acute care to post hospital skilled nursing care.

175. Medicare reimburses CAHs at 101 percent of their reasonable costs for providing skilled nursing services to beneficiaries, rather than at rates set by Medicare's prospective pay system, which is the basis on which skilled nursing facilities and non-CAHs are paid.

176. According to a Department of Health and Human Services OIG study from March of 2015, for the 6-year period reviewed, Medicare spent, on average, almost four times more for swing-bed services at CAHs than for similar services at alternative

facilities. In 2010 swing-bed reimbursement at CAHs were $1,261 per day compared to $273 per day for similar services at alternative facilities (non-CAHs). *Medicare Could Have Saved Billions on Swing-Bed Services at Critical Access Hospitals (A-05-12-00046).*

Requirements for discharge planning

177. Hospitals participating in the Medicare program and other federal healthcare programs must meet certain requirements related to the discharge planning process.

178. Section 1395x(ee) of the Social Security Act requires the following:

> **(D)** A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate post-hospital services, including hospice care and post-hospital extended care services, and the availability of those services, including the availability of home health services through individuals and entities that participate in the program under this subchapter and that serve the area in which the patient resides and that request to be listed by the hospital as available and, in the case of individuals who are likely to need post-hospital extended care services, the availability of such services through facilities that participate in the program under this subchapter and that serve the area in which the patient resides.
>
> * * * *
>
> **(H)** Consistent with section 1395a of this title, the discharge plan shall—
>
> > **(i)** not specify or otherwise limit the qualified provider which may provide post-hospital home health services, and
> >
> > **(ii)** identify (in a form and manner specified by the Secretary) any entity to whom the individual is referred in which the hospital has a disclosable financial interest (as specified by the Secretary consistent with section 1395cc(a)(1)(S) of this title) or which has such an interest in the hospital.

179. More specifically, 42 C.F.R. § 482.43 provides for conditions of participation related to discharge planning for hospitals, as follows:

> **(6)** The hospital must include in the discharge plan a list of HHAs or SNFs that are available to the patient, that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, in the geographic area requested by the patient. HHAs must request to be listed by the hospital as available.
>
> > **(i)** This list must only be presented to patients for whom home health care or post-hospital extended care services are indicated and appropriate as determined by the discharge planning evaluation.
> >
> > **(ii)** For patients enrolled in managed care organizations, the hospital must indicate the availability of home health and post-hospital extended care services through individuals and entities that have a contract with the managed care organizations.
> >
> > **(iii)** The hospital must document in the patient's medical record that the list was presented to the patient or to the individual acting on the patient's behalf.
>
> **(7)** The hospital, as part of the discharge planning process, must inform the patient or the patient's family of their freedom to choose among participating Medicare providers of post-hospital care services and must, when possible, respect patient and family preferences when they are expressed. The hospital must not specify or otherwise limit the qualified providers that are available to the patient.

Channeling post-hospital extended care patients to CAH to inflate swing-bed reimbursements

180. In violation of the Medicare requirements for discharge planning, the Hospital Defendants have devised a scheme to inflate their billings by channeling patients discharged from its non-CAHs to Defendant Brookville Hospital for post-hospital extended care services.

181. Because Brookville Hospital is a certified CAH, Penn Highlands Healthcare can charge the Medicare program four times the amount that it could

otherwise expect to receive for post-hospital extended care as swing-bed services provided at its other hospitals by discharging its patients to Brookville Hospital.

182. In 2010 DRMC executed an affiliation agreement with Brookville Hospital and became the sole member or shareholder of the Brookville Companies, including Brookville Regional Health Services, Brookville Hospital Foundation and Brookcare. The following year, in October of 2011, DRMC entered into an affiliation with Clearfield Hospital to form Penn Highlands Healthcare. As of June 30, 2013, Penn Highlands Healthcare acquired Elk Regional Health System.

183. With the various hospitals under common ownership and control, the Hospital Defendants embarked on a plan to channel their post-hospital extended care discharges to Brookville for increased reimbursements, even though such discharges violated patient preferences, and even though swing-bed alternatives were available at other hospitals or a skilled nursing facilities.

184. To carry out the scheme, the Hospital Defendants failed to provide Medicare patients with a list of alternate facilities, denied those patients post-hospital care as swing-bed services at it's non-CAH facilities, and directed those patients to swing-bed services at Brookville Hospital.

185. For example, Medicare patient VM was transferred to Brookville Hospital for swing-bed services following a total knee replacement surgery at DRMC on September 1, 2015, even though swing-bed services were available on this date at DRMC. VM was not provided a choice to receive post-hospital extended care services at DRMC or at any other available facilities.

186. In another example, Medicare patient GLS was treated for sepsis with a UTI as an inpatient at DRMC from May 3, 2016 to May 8, 2016. While GLS's chart indicates that post-hospital extended care was not medically necessary, he was nevertheless improperly discharged and transferred for swing-bed services at Brookville, even though the same swing-bed services were available at DRMC. GLS received swing-bed services from May 8, 2016 to May 23, 2016. Not only was GLS referred for unnecessary services, he was not given a choice and was incorrectly told that DRMC did not have swing-bed services.

THE UNITED STATES HAS BEEN DAMAGED

187. As more particularly described above, defendants have profited and the United States has been damaged monetarily by the practices used by Defendants to make false claims to federal health care programs for payment and reimbursement. Defendants have submitted many false claims for excessive and unauthorized payments and reimbursements and have obtained excessive compensation from the United States as a result.

KNOWLEDGE AND RETALIATION

188. As indicated above, Relators first discovered that the Hospital Defendants were improperly billing non-physician services, when the issue was raised by Relator Simpson in her capacity as the interim Executive Director, and Vice President of the Board of Directors of the Free Medical Clinic in August of 2014.

189. In response to a question regarding the proper billing of CRNPs at the clinic, Joanne Genevaro, Penn Highlands Healthcare's Director of Revenue Management incorrectly advised that all billings to Medicaid for services done by CRNP's or PA's

have to be signed off on by the supervising physician and billed under the physician's ID#" (Genevro, 2014)."

190. Subsequently, upon further challenge, Genevaro acknowledged that non-physician practitioners could enroll in the federal healthcare programs, obtain their own NPI number, and bill independent of a supervising physician.

191. Relator Simpson persisted in her investigation by questioning her husband, a hospitalist employed by Brookville Hospital, and other physicians employed by the Defendant Hospitals. Relator Simpson's further investigation confirmed that even after Joanne Genevaro was made aware of the proper procedure for billing CRNP and PA services to the federal health insurance programs, the Hospital Defendants continued to improperly bill the services of non-physician practitioners.

192. Relator Simpson also discussed the improper billings with Jim Curtis, a member of the Penn Highlands Healthcare's Board of Directors, who assured Relator Simpson that the billing issues were under review and that they would be properly addressed.

193. Relator Simpson also discussed the improper billings with Tuesdae Stainbrook and Jonathan Pope, who were at that time employed by DRMC as infectious disease specialists. Dr. Pope was at that time a member of the DRMC Board of Directors.

194. Relator Stainbrook and Relator Pope assisted Realtor Simpson with her investigation, not only confirming that the Hospital Defendants were improperly billing non-physician practitioner services, but also uncovering other compliance issues that they believed put the hospitals and their patients at risk, including violations of the Stark Statute and the Anti-kickback Statute Stark and misuse of Rural Health Clinic and

Critical Access Hospital designations. They also found that budgetary cuts had resulted in reductions in the housekeeping staff, which in turn led to an increase in the rate of hospital infections.

195. Rather than correct the compliance issues identified by the Relators, the Defendants responded by retaliating against the Relators.

196. On November 14, 2014, John Sutika notified Relator Stainbrook that DRMC intended to not renew its employment contract with her.

197. Over the next several months DRMC engaged in bad faith negotiations by offering terms for a new employment contract that were so onerous so as to constitute a constructive discharge.

198. By letter dated August 28, 2015, from her counsel, Relator Stainbrook informed DRMC that the terms offered were unacceptable and that she was leaving her employment with DRMC to start a private practice.

199. As a result of DRMC's retaliation and constructive discharge of Relator Stainbrook, she has sustained damages, including a loss of income and damage to her professional reputation.

200. On May 7, 2015, Dr. Pope's employment was terminated. On that date John Sutika, President of DRMC, informed Dr. Pope that DRMC would not renew his employment contract.

201. As a result of DRMC's retaliation and termination of Relator Pope, he has sustained damages, including a loss of income and damage to his professional reputation.

COUNT I
Federal False Claims Act 31 U.S.C. § 3729(a)(1)(A)

202. Relators re-allege and incorporate by reference the allegations contained in the previous paragraphs of this complaint.

203. This is a claim for treble damages, civil penalties and attorney's fees, under the Federal False Claims Act, 31 U.S.C. §§ 3729, *et seq.* as amended.

204. By means of the acts described above, defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the United States. The United States, unaware of the falsity of the claims made, and in reliance on the accuracy thereof, paid for claims that would otherwise not have been allowed.

205. By reason of these payments, the United States has been damaged, and continues to be damaged, in a substantial amount.

206. Said claims were presented with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

COUNT II
Federal False Claims Act 31 U.S.C. § 3729(a)(1)(B)

207. Relators re-allege and incorporate by reference the allegations contained in the previous paragraphs of this complaint.

208. This is a claim for treble damages, civil penalties and attorney's fees, under the Federal False Claims Act, 31 U.S.C. §§ 3729, *et seq.* as amended.

209. By means of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements material to a false or fraudulent claim in violation of 31 U.S.C. § 3729(a)(1)(B). The United States, unaware of the

falsity of the records and statements, and in reliance on the accuracy thereof, paid for claims that would otherwise not have been allowed.

210. By reason of these payments, the United States has been damaged, and continues to be damaged, in a substantial amount.

211. Said false records or statements were made with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

COUNT III
Federal False Claims Act - 31 U.S.C. § 3729(a)(1)(G)

212. Relators re-allege and incorporate by reference the allegations contained in preceding paragraphs, as though fully set forth herein.

213. This is a claim for penalties and treble damages under the Federal False Claims Act, 31 U.S.C. §§ 3729, et seq., as amended.

214. Through the acts described above, Defendants have knowingly made, used, or caused to be made or used, false records or statements and concealed, avoided, or decreased an obligation to pay or transmit money or property to the federal government, within the meaning of 31 U.S.C. § 3729(a)(1)(G).

215. An overpayment from a government program received by a provider in excess of the amount that is due and payable, including any payment for services that are not reasonable and necessary in accordance with the Medicare rules, must be promptly remitted by the provider.

216. Even when an overpayment is received through an innocent billing error or through a mistake of the contractor, 42 U.S.C. § 1320a-7k(d)(1) provides that

"returning the overpayment . . . is an obligation as defined in 3729(b)(3) of title 31 for purposes of section 3729 of such title."

217. Defendants are aware that the conduct described herein has resulted in the submission of claims to government healthcare programs for payment to which Defendants are not entitled. Defendants have knowingly and wrongfully retained such overpayments.

218. On and after May 24, 2010, the effective day of the legislation that established subsection 7k(d)(1) referred to above, each day that Defendants have retained such an overpayment is a separate violation of the FCA.

COUNT IV
Federal False Claims Act - 31 U.S.C. § 3730(h)
Stainbrook v. DRMC

219. Relators re-allege and incorporate by reference the allegations contained in preceding paragraphs, as though fully set forth herein.

220. Each of the acts of Defendant DRMC, in discriminating against Relator Stainbrook, by imposing unreasonable terms and conditions for the renewal of her employment contract, violates the provisions of 31 U.S.C. § 3730 (h) prohibiting discrimination against employees who investigate and/or report violations of the False Claims Act.

221. As a direct and proximate result of the foregoing, Relator Stainbrook has lost wages, healthcare benefits, job security, together with all future benefits appurtenant to her position with Defendant DRMC. In addition, Relator Stainbrook has sustained damage to her reputation and suffered severe physical and emotional distress. Relator Stainbrook is entitled to all relief necessary to make her whole, including reinstatement,

two times the amount of back pay, and compensation for special damages, including all litigation costs and attorneys fees.

COUNT V
Federal False Claims Act - 31 U.S.C. § 3730(h)
Pope v. DRMC

222. Relators re-allege and incorporate by reference the allegations contained in preceding paragraphs, as though fully set forth herein.

223. Each of the acts of Defendant DRMC, in harassing Relator Pope and eventually refusing to renew his employment contract, violates the provisions of 31 U.S.C. § 3730 (h) prohibiting discrimination against employees who investigate and/or report violations of the False Claims Act.

224. As a direct and proximate result of the foregoing, Relator Pope has lost wages, job security, together with all future opportunities appurtenant to his position with Defendant DRMC. In addition, Relator Pope has sustained damage to his reputation and suffered severe physical and emotional distress. Relator Pope is entitled to all relief necessary to make him whole, including two times the amount of back pay, and compensation for special damages, including all litigation costs and attorneys fees.

WHEREFORE, Relators, Tuesdae Stainbrook, Mary Simpson and Jonathan Pope, respectfully request this Honorable Court to enter judgment against Defendants, as follows:

a. That the United States be awarded damages in the amount of three (3) time the actual damages suffered by the United States Government as a result of the false claims and fraud alleged within this Complaint, as the Civil False Claims Act, 31 U.S.C. §§ 3729 et seq., provides;

b. Civil penalties against the Defendant equal to $11,000 for each violation of 31 U.S.C. § 3729;

c. *Qui tam* Relators/Plaintiffs be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d);

d. *Qui tam* Relators/Plaintiffs be awarded all costs and expenses of this litigation, including attorney's fees and costs of court;

e. *Qui tam* Relators/Plaintiffs be awarded all other allowable damages, and;

f. All other relief on behalf of the Relators/Plaintiffs or the United States Government to which they may be entitled and that the Court deems just and proper.

MOREOVER, Relators, Tuesdae Stainbrook and Jonathan Pope, on their own behalf, demand and pray that an award be made in their favor for an amount equal to two times Relators' accrued back pay, with interest, lost earnings, bonuses, deferred compensation and other employment benefits, plus expenses incurred seeking substitute employment and for an amount necessary to make Relators whole, including without limitation compensation for deteriorating physical health, mental anguish, suffering, humiliation, pain, discomfort, anxiety, and emotional distress.

DEMAND FOR JURY TRIAL

Relators, on behalf of themselves and the United States, demand a jury trial on all claims alleged herein.

Dated: October 11, 2016

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